UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. RENÉE MARIE BUMB**
THIS DOCUMENT RELATES TO: *Gaston Roberts et al. v. Zhejiang Huahai Pharmaceutical Co., et al.*, Case No. 1:20-cv-00946	

PLAINTIFFS' BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE THE OPINIONS OF PLAINTIFFS' EXPERT JOHN RUSSO, M.D.

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PRELIMINARY STATEMENT

John Russo, M.D. is an internist who was a prescribing doctor of Valsartan during the time period when the ZHP pills were contaminated with NDMA, and was one of the many physicians who was required to transition his patients to alternative medications and treatments when the FDA recall was announced. Dr. Russo authored a detailed report that sets forth his background and experience, and details his opinions, all of which are based on his actual practice of medicine while applying and explaining the pivotal FDA statements announcing the recall of the contaminated medication. (Defs.' Ex. 1).[1]

Dr. Russo's opinions are focused on the physicians who prescribed Valsartan. The learned intermediaries like the prescribing doctor in this case, Dr. Robichaux. This is virtually ignored by the defense. His opinions can be generally grouped into three categories. First, he opines that the information/risk warnings provided by ZHP prior to the recall were inadequate to inform prescribing physicians of the risk benefit profile for the medication because of the failure to disclose that the pills contained the probable human carcinogen NDMA. Second, Dr. Russo opines and

[1] Defendants point out that Dr. Russo initially failed the board certification exam, which is salacious but of no import. He is board certified, and has risen to significant administrative positions in a large hospital system, including Section Chief of the Department of Medicine at Cooperman/RWJ St. Barnabas, which is a testament to the respect he has earned in his field. (Dr. Russo R. 1-2, Ex. A (Defs.' Ex. 1); Dr. Russo Dep. Tr. 258:15-261:22 (Defs.' Ex. 2)).

explains how the standard of care applied to require a reasonable prescribing physician to transition his or her patients to alternative medications not contaminated with NDMA, and how this played out in actual clinical practice. Third, Dr. Russo opines that the risk-benefit analysis required by the standard of care for a reasonable prescribing physician would never have permitted the knowing prescription of NDMA contaminated valsartan in light of the risk posed and the availability of safer alternative medications and treatments.

Defendants predictably attack Dr. Russo's credentials and highlight isolated statements during his deposition without providing the full context of his statements. Defendants leave out the facts that Dr. Russo is a board-certified internist, he teaches residents, is the section chief for the Department of Medicine at RWJ Cooperman St. Barnabas Medical Center, and is a member of the Formulary Committee of the hospital as well. Dr. Russo acknowledged that he is not a regulatory expert, that he is not a causation expert, and that he did not independently evaluate the validity of the opinions of Plaintiffs' liability expert Dr. Hecht, which he relied on for background and context for how and why the contamination occurred. Of course, if he had testified to the contrary, the Defendants would criticize him for attempting to be what he is not. Since his opinions are limited to what he knows and did as a prescribing doctor, these attacks are red herrings.

Defendants also criticize Dr. Russo for confirming that the standard he applied

to his opinion regarding the inadequacy of the risk information provided by ZHP is in accordance with the federal labeling standard requiring that safety risks be disclosed, because he is not a regulatory expert. Dr. Russo is absolutely qualified to interpret that standard from the perspective of a prescribing physician who relies on warning information in treating his patients. The point that matters is that the applicable standard was considered and relied on—and confirmed to be fully consistent with the standard applied by practitioners—the learned intermediaries.

Defendants' motion is largely premised on a mischaracterization of what Dr. Russo did, pretending that he tried to claim he was a regulatory expert, offered ethics opinions, and offered legal conclusions. He did none of that. His opinions are valid and fit the case. He can explain to the jury how a physician selects a blood pressure medication for a patient, the impact on the risk benefit analysis and informed consent from NOT being told that valsartan sold by ZHP contained NDMA, and the meaning and application of the FDA statement to physicians like him directing the physicians to transition their patients from the contaminated medication to alternatives. The motion should be denied.

LEGAL ARGUMENT

I.

DR. RUSSO'S WARNING OPINIONS SHOULD BE PERMITTED

A. Dr. Russo Is Qualified to Offer His Opinions.

Dr. Russo is qualified to offer his opinions regarding the inadequacy of the warnings/risk information provided by ZHP from the perspective of a prescribing physician. He is literally one of the physicians that information was provided for—the learned intermediary who must evaluate and apply the prescribing and risk information provided by the manufacturer to counsel and make treatment recommendations to patients. *Blackburn v. Shire U.S., Inc.*, 380 So. 3d 354, 359 (Al. 2022).

It is true that he is not a regulatory expert, but that is not a disqualifying fact because he is not pretending to be a regulatory expert. Rather, he is a practicing internal medicine clinician with actual experience in relying on the information provided by ZHP, and actual experience in applying the FDA recall notice in the care of actual patients. He need not be a regulatory expert or have experience writing drug warnings for industry. *See Arevalo v. Coloplast Corp.*, No. 3:19CV3577-TKW-MJF, 2020 WL 3958505, at *20 (N.D. Fla. July 7, 2020) (rejecting the argument that the expert needed experience drafting labels because "he has ample experience interpreting IFUs over the course of his career"), *aff'd sub nom.*, *Arevalo*

v. Mentor Worldwide LLC, No. 21-11768, 2022 WL 16753646 (11th Cir. Nov. 8, 2022).

Moreover, Dr. Russo teaches residents and holds significant administrative positions at a large New Jersey hospital, Robert Wood Johnson Cooperman Barnabas Medical Center, including Section Chief for the Department of Medicine with oversight over many physicians, and member of the hospital's Formulary Committee, which is responsible for determining what medications to include in the hospital's medication inventory. In those roles, he has direct knowledge and experience applying risk benefit analyses to the choice of blood pressure medications to be recommended to patients, including with regard to the Valsartan at issue in this case. He also teaches medical students and residents, including how to utilize prescribing and risk information provided by drug manufacturers in the clinical treatment of patients. (*See, e.g.*, Dr. Russo Dep. Tr. 258:3-261:22 ("the formulary is looking at all of this data to make certain that we have the safest and the latest versions of all of these medication choices for our medical staff"), 270:7-11 ("I educate the residents, medical students about the different sources of information regarding medication prescriptions, about assessing patients").

Dr. Russo's actual experience with the medication at issue, including the information provided by ZHP, and then by the FDA, and his oversight of the actions of hundreds or thousands of other physicians, including those he has taught, clearly

qualifies him to testify with regard to the adequacy of that information from the perspective of a prescribing learned intermediary.

B. Dr. Russo Applied A Reliable Methodology.

Defendants fail to acknowledge that Dr. Russo's methodology is built from the perspective of a physician—the learned intermediary who must evaluate and apply the prescribing and risk information provided by the manufacturer to counsel and make treatment recommendations to patients. *Blackburn v. Shire U.S., Inc.*, 380 So. 3d 354, 359 (Al. 2022); *See In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2020 WL 6887885, at *26 (E.D. Pa. Nov. 24, 2020) ("[T]he Third Circuit has recognized that a doctor's experience alone renders him a reliable witness to testify about a reasonable standard of care or what a reasonable physician would do," including "'what a reasonable doctor *should* know' or 'how a reasonable doctor would interpret [a] safety warning'") (citing *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 405–07 (3d Cir. 2003)); *Crockett v. Luitpold Pharms., Inc.*, No. CV 19-276, 2023 WL 2162600, at *3 (E.D. Pa. Feb. 22, 2023) ("Doctors are able to rely on their experience to opine about what a reasonable doctor should know or how a reasonable doctor would interpret a drug warning. Moreover, medical experts can testify as to the adequacy of drug labeling and warnings based on their experience as physicians." (citation omitted)).

Dr. Russo considered the labels representing that the medication was the

approved form of Valsartan, the FDA statements disclosing the contamination and directing that patients be switched to alternative treatments—and why, and his experience in utilizing prescribing information from manufacturers (including for Valsartan), and confirmed that his understanding of the manufacturer's duty is in line with the FDA standard that requires the dissemination of risk information. (Dr. Russo R. 2-5, 8-11 (Defs.' Ex. 1); Dr. Russo Dep. Tr. 251:11-252:25, 257:7-12; 262:25-263:17 (Defs.' Ex. 2)). Ignored by the defense, but indisputable, is the fact that the NDMA contamination was determined by the FDA to be fundamental risk information that had to be disclosed—of such significance that the disclosure triggered a recall and instructions to clinicians to switch their patients to different medications and treatments.

Defendants are clearly wrong that Dr. Russo lacks a basis for his opinion that the FDA was not endorsing the safety of ZHP's contaminated valsartan by advising patients to obtain a replacement prescription of uncontaminated valsartan instead of immediately stopping the use of the drug. Dr. Russo explained his reasoning based on his experience and expertise as a doctor at whom the FDA statement was directed:

> The FDA's recommendation that patients continue to take the contaminated pills until their physicians could prescribe replacement therapy was not an endorsement of the safety of the contaminated pills. Instead, it was the product of a straightforward risk-benefit analysis comparing the short-term risk of a disabling or fatal cardiac or vascular event due to abrupt cessation of hypertension therapy as against the longer-term risk of

> cancer. The FDA made the reasonable determination that the immediate risk had to be prioritized, with the expectation per the announcement that patients would promptly seek and be directed to safe alternative therapies, of which there were many.

(Dr. Russo. R. 8). This complies even with Defendants' own case. *Staub v. Breg, Inc.*, No. CV 10-02038-PHX-FJM, 2012 WL 1078335, at *3 (D. Ariz. Mar. 30, 2012) (allowing expert testimony involving "analysis, opinion, or expertise when testifying about the regulatory process and history of" the product at issue, and noting that objections on this basis should be reserved for trial). The Court also has found that the defense cannot assert that the FDA statement was an endorsement of the safety of the contaminated pills. (7/23/2024 Tr. 189:17-24, 190:17-193:5).

Interestingly, Defendants cite *Hines v. Wyeth* for the proposition that an expert should be excluded for "fail[ing] to cite a single rule or regulation that would require defendants to act as she suggests they should have, nor does she in any other way provide the grounds for her conclusion that a responsible manufacturer would have behaved differently," while simultaneously criticizing Dr. Russo's references to the regulations applicable to Defendants' conduct. *Hines v. Wyeth*, No. CIV.A. 2:04-0690, 2011 WL 2680842, at *5 (S.D.W. Va. July 8, 2011). Dr. Russo is not a regulatory expert, but Defendants do not dispute that 21 C.F.R. § 201.57 and 21 C.F.R. § 314.81 applied to their conduct in this case. Dr. Russo further explained that these regulations are "fully consistent with the standard I have applied in

forming my opinions here, and the expectations of reasonable physicians in clinical practice." (Dr. Russo R. 4). Defendants cannot credibly criticize application of the applicable standard, when also arguing that failure to apply that standard would also warrant exclusion.

Dr. Russo also considered and relied on the testimony of the prescribing physician in this case, Dr. Robert Robichaux, who testified that if he had been aware of the NDMA contamination he would have recommended a different medication for Mr. Roberts. (Dr. Russo R. 10 ("For example, Dr. Robichaux, who prescribed the Valsartan to Mr. Roberts, confirmed in his deposition that he would not have prescribed contaminated Valsartan to Mr. Roberts, and if he had known of the contamination, he would have prescribed a different medication."); Dr. Russo Dep. Tr. 57:12-14).

Defendants are mistaken that Dr. Russo cannot discuss this and other parts of the record of this case in explaining his opinions. If Dr. Russo had not confirmed that he was aware of the testimony of the learned intermediary, and had not considered ZHP's own statements on the issue, the defense would accuse him of promoting a net opinion. This whipsaw approach dressed up as a *Daubert* motion is not valid. ZHP's own case states: "An expert may testify to a review of internal documents for the purpose of explaining the basis for his or her admissible opinions ... [b]ut simply parroting [d]efendant's corporate documents or offering a narrative

account of events from them will not be helpful to the jury." *O'Bryant v. Johnson & Johnson*, No. CV202361MASDEA, 2022 WL 7670296, at *13 (D.N.J. Oct. 13, 2022). Dr. Russo did not parrot statements. He recited the key facts he relied on.

Ironically, Defendants appear to be arguing that no expert is needed since the failure to warn and the gravity of that failure is established, which is factually accurate. One of the lines of questioning of Dr. Russo at his deposition intended to undermine his opinions illustrates the gravity of ZHP's failure to warn of the contamination. Defense counsel made the point that if ZHP had disclosed the contamination earlier this information would not have been considered in prescribing decisions but rather would have triggered the recall. (Dr. Russo Dep. Tr. 135:4-137:9). This is not a disqualifying fact, but rather confirmation of the gravity of ZHP's failure. And ZHP misses the fact that the failure to warn claim extends not just to the labeling for the pills, but also to the failure to provide that information to the FDA—which then would transmit that information to physicians and patients, as occurred in 2018. That duty is not disputed by ZHP—in fact their own corporate representative admitted that disclosure to the FDA was required. (Min Li 3/10/2021 Dep. Tr. 224:21-225:4 (Ex. 1 to Adam M. Slater's certification in support of this brief)).

Dr. Russo's reliance/reference to the reports of other experts is proper and a matter for cross examination, not exclusion. Dr. Russo relied on Dr. Hecht's

rendition of what happened and why, which is foundational information. Defendants cannot be suggesting that Dr. Russo should have replicated the work of an expert in organic chemistry and nitrosamines. *Leese v. Lockheed Martin Corp.*, 6 F. Supp. 3d 546, 553 (D.N.J. 2014) ("Experts 'may use a mix of objective data and subjective analysis from another expert to ... create an admissible report,' and the testifying expert's knowledge regarding the underlying facts 'go[es] to the weight accorded to [that expert's] report and testimony, rather than its admissibility.'"); *S.Y. v. Roman Cath. Diocese of Paterson*, No. 20CV2605 (EP) (CLW), 2024 WL 1231333, at *7 (D.N.J. Mar. 21, 2024); *Callas v. Callas*, No. CV 14-7486, 2020 WL 3468084, at *8 (D.N.J. June 25, 2020) ("In sum, Rinaldi's testimony, based on his report, is admissible. To the extent that Defendants believe Rinaldi made errors in his own analysis, or that his reliance upon Morris's analysis was unreasonable, Defendants are certainly free to cross-examine Rinaldi on those issues.").

C. Dr. Russo Does Not Offer Legal Opinions.

Defendants incorrectly claim Dr. Russo offers legal opinions that ZHP "failed to warn as a matter of law." (Defs.' Br. 8). However, the phrases "failed to warn" or "fail to warn" do not appear once in his report and are only used by defense counsel in his deposition—Dr. Russo very clearly discussed the inadequacy of the warnings and information provided to physicians. (*See* Dr. Russo R.; Dr. Russo Dep. Tr. 142:19-23). Defendants own case—*Arevalo v. Coloplast Corp.*—clearly

differentiates between impermissible expert testimony that a defendant "failed to warn" and permissible testimony that a warning was "adequate" or "inadequate" and related permissible opinions on "the standard of care in the industry." No. 3:19CV3577-TKW-MJF, 2020 WL 3958505, at *20-21 (N.D. Fla. July 7, 2020), *aff'd sub nom. Arevalo v. Mentor Worldwide LLC*, No. 21-11768, 2022 WL 16753646 (11th Cir. Nov. 8, 2022). All of Dr. Russo's opinions are permissible based on this distinction, as he couches them in terms of adequacy and the information need for a reasonable physician to comply with the standard of care in his industry. As stated above, it is undisputed that ZHP did not warn of the presence of NDMA in its valsartan before July 13, 2018. An expert cannot be excluded for refencing such an undisputed fact, and discussing the ramifications. *Brill v. Marandola*, 540 F. Supp. 2d 563, 570 (E.D. Pa. 2008) (permitting hypotheticals to be stated as "objective facts" if based on "undisputed" facts).

D. Dr. Russo Does Not Offer Ethical Opinions.

ZHP conflates opinions of wrongdoing with ethical opinions. Dr. Russo does not state that ZHP acted unethically, and does not offer "[p]ersonal views on corporate ethics and morality." *In re Baycol Prods. Liab. Litig.*, 532 F. Supp. 2d 1029, 1053 (D. Minn. 2007). His opinions are focused on ZHP's failure to disclose the presence of NDMA in its valsartan in accordance with Alabama state law and the applicable FDA regulations. Unlike in *In re Welding Fune Products Liability*

Litigation, Dr. Russo does not opine that "a manufacturer's duty to warn 'goes beyond a legal duty; [it is also] a moral obligation." *In re Welding Fume Prods. Liab. Litig.*, No. 1:03-CV-17000, 2005 WL 1868046, at *21 (N.D. Ohio Aug. 8, 2005). The Court should not exclude the cited opinions.

CONCLUSION

For the foregoing reasons, Defendants' motion to preclude certain of Dr. Russo's opinions should be denied.

Respectfully,

By: /s/ *Adam M. Slater*

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CERTIFICATE OF SERVICE

I hereby certify that on June 6, 2025, I electronically filed this brief and my supporting certification with the Clerk of the Court using CM/ECF system, which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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Dated: June 26, 2025